IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
EASTERN DIVISION
No. 4:12-CV-109-D

FARMVILLE DISCOUNT DRUG, INC., et al.,	)	
Plaintiffs,	)	
v.	)	**ORDER**
KATHLEEN SEBELIUS, Secretary Health and Human Services, et al.,	)	
Defendants.	)	

Plaintiffs, four independent pharmacy companies operating in North Carolina, challenge the Preferred Pharmacy Rule, 42 C.F.R. § 423.120(a)(9) [D.E. 1]. Plaintiffs sued the Department of Health and Human Services ("HHS"), HHS Secretary Kathleen Sebelius, in her official capacity, the Centers for Medicare and Medicaid Services ("CMS"), and CMS Administrator Marilyn Tavenner, in her official capacity (collectively "defendants") and seek declaratory and injunctive relief. Compl. ¶¶ 7–10. Essentially, plaintiffs argue that the Preferred Pharmacy Rule violates the Any Willing Provider Rule (42 U.S.C. § 1395w-104(b)(1)(A)). On May 8, 2012, defendants filed a motion to dismiss for lack of jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1) [D.E. 18]. Defendants contend that this court lacks subject-matter jurisdiction because plaintiffs failed to present their claims to CMS and exhaust the administrative process before filing suit. Plaintiffs responded in opposition, and defendants replied. As explained below, the court lacks subject-matter jurisdiction and grants the motion to dismiss.

I.

In 2003, Congress expanded Medicare by enacting Part D, which pertains to prescription drug

costs. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 42 U.S.C.) ("Part D Act"). The Part D Act permits individuals otherwise eligible for Medicare to enroll in a prescription drug plan ("PDP") that supplements their Medicare drug coverage. See Compl. ¶ 17; see also 42 U.S.C. § 1395w-101(a). The Part D Act permitted private organizations, such as health insurance carriers, to sponsor PDPs. See 42 U.S.C. §§ 1395w-111 to 112. All PDPs must comply with the so-called "any willing pharmacy" provision, which requires that "any pharmacy that meets the terms and conditions" of a PDP be allowed to participate in that PDP. 42 U.S.C. § 1395w-104(b)(1)(A); see Compl. ¶ 18.

A pharmacy meeting a PDP's terms and conditions is an in-network pharmacy. A pharmacy that does not meet a PDP's terms and conditions is an out-of-network pharmacy. Under the Part D Act, PDP enrollees may receive co-payment discounts if they fill their prescriptions at in-network pharmacies. See 42 U.S.C. § 1395w-104(b)(1)(B). Plaintiffs are in-network pharmacies that participate in Part D. See Compl. ¶¶ 3–6.

Beyond the distinction between in-network and out-of-network pharmacies, Part D, as implemented by regulations, also distinguishes between in-network preferred and in-network non-preferred pharmacies. Congress delegated the authority to enact regulations to administer Part D to the HHS Secretary, who in turn delegated the power to the CMS Administrator. See 42 U.S.C. § 1395hh(a). CMS then promulgated the so-called Preferred Pharmacy Rule. See 42 C.F.R. § 423.120(a)(9); 70 Fed. Reg. 4194, 4254 (Jan. 28, 2005).

The Preferred Pharmacy Rule applies to in-network pharmacies. See 42 C.F.R. § 423.120(a)(9). The Preferred Pharmacy Rule permits PDPs to differentiate in-network pharmacies further between preferred and non-preferred pharmacies. See id. Prescriptions that preferred pharmacies fill may be eligible for reduced co-payments compared to co-payments for prescriptions

filled at non-preferred pharmacies. See id. The PDP sponsor bears the cost of co-payment reductions. See id.

Plaintiffs were not classified as preferred pharmacies. Compl. ¶ 33. As a result, plaintiffs allege that they have lost—and continue to lose—business to preferred pharmacies. Id. ¶ 35. Citing section 706(2) of the Administrative Procedure Act, 5 U.S.C. § 706(2), plaintiffs contend that CMS's Preferred Pharmacy Rule is arbitrary and capricious, violates the statute's Any Willing Provider Rule, and was promulgated in excess of CMS's statutory mandate. See Compl. ¶¶ 37–38. Plaintiffs seek a declaratory judgment that the Preferred Pharmacy Rule ("Rule") is invalid and seek to enjoin defendants from approving PDPs that include preferred pharmacies. See id. (request for relief). Defendants respond that this court lacks subject-matter jurisdiction because plaintiffs failed to present their claim to CMS and to exhaust the administrative process before filing suit.

II.

Subject-matter jurisdiction concerns "the courts' statutory or constitutional power to adjudicate the case." Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 89 (1998); Holloway v. Pagan River Dockside Seafood, Inc., 669 F.3d 448, 453 (4th Cir. 2012). Congress sets the bounds of the lower federal courts' subject-matter jurisdiction. See Kontrick v. Ryan, 540 U.S. 443, 453 (2004); Steel Co., 523 U.S. at 101. Although Congress generally granted jurisdiction to hear cases involving federal questions, see 28 U.S.C. § 1331, it has limited courts' subject-matter jurisdiction for specific types of cases. See, e.g., Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 5–9 (2000); Piney Run Pres. Ass'n v. Cnty. Comm'rs of Carroll Cnty., 523 F.3d 453, 456 (4th Cir. 2008).

Plaintiffs must establish subject-matter jurisdiction. See Piney Run, 523 F.3d at 459; Richmond, Fredericksburg & Potomac R.R. v. United States, 945 F.2d 765, 768 (4th Cir. 1991);

Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1982). When subject-matter jurisdiction is challenged, a court may consider evidence beyond the allegations in the complaint to resolve the jurisdictional issue. See Richmond, 945 F.2d at 768; Bain, 697 F.2d at 1219. If the court determines that it lacks subject-matter jurisdiction, it must dismiss the complaint. See, e.g., Arbaugh v. Y & H Corp., 546 U.S. 500, 514 (2006).

Plaintiffs assert jurisdiction pursuant to 28 U.S.C. § 1331. See Compl. ¶ 11. However, special jurisdictional provisions apply to actions arising under the Medicare statutes. See 42 U.S.C. § 405(h); see also 42 U.S.C. § 1395ii (incorporating 42 U.S.C. § 405(h) into the Medicare statutes); Ill. Council, 529 U.S. at 9 ("Section 1395ii makes [section] 405(h) applicable to the Medicare Act to the same extent as it applies to the Social Security Act." (quotations omitted)). An action arises under the Medicare statutes if it is "inextricably intertwined" with a claim for Medicare benefits, which is a "broad test." Heckler v. Ringer, 466 U.S. 602, 614–15 (1984); see, e.g., Weinberger v. Salfi, 422 U.S. 749, 760–61 (1975); Puerto Rican Ass'n of Physical Med. & Rehab., Inc. v. United States, 521 F.3d 46, 48 (1st Cir. 2008) ("[A] claim arises under the . . . Medicare Act if the standing and the substantive basis for the claim derive from that statute." (quotations omitted)). CMS promulgated the Rule to implement Part D, and plaintiffs challenge to the Rule arises under the Medicare statutes. Because plaintiffs' action arises under the Medicare statutes, section 405(h) applies. Section 405(h) provides that a party may not sue under 28 U.S.C. § 1331 without first complying with the administrative review procedures in 42 U.S.C. § 405(g). See 42 U.S.C. § 405(h).

In Illinois Council, the Supreme Court construed the jurisdictional bar in section 405(h). There, a nursing-home association challenged Medicare-related regulations as violating federal law and the Constitution. The Court observed that "the bar of [section] 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies.'" Ill.

Council, 529 U.S. at 12; see, e.g., Salfi, 422 U.S. at 757; Hopewell Nursing Home, Inc. v. Schweiker, 666 F.2d 34, 38 (4th Cir. 1981) (recognizing that section 405(h) "is more than mere codification of the exhaustion of remedies doctrine"). Section 405(h) "demands the 'channeling' of virtually all legal attacks through the agency." Ill. Council, 529 U.S. at 13.

Despite section 405(h)'s great breadth, the Court acknowledged in Illinois Council that section 405(h) was not impregnable. Section 405(h)'s bar does not apply in those few cases where it "would not lead to a channeling of review through the agency, but would mean no review at all." Id. at 17; see GOS Operator, LLC v. Sebelius, 843 F. Supp. 2d 1218, 1224–25 (S.D. Ala. 2012) ("This 'no review at all' exception . . . is both narrowly circumscribed and rarely applicable."). According to the Court, "the question is whether, as applied generally to those covered by a particular statutory provision, hardship likely found in many cases turns what appears to be simply a channeling requirement into complete preclusion of judicial review." Ill. Council, 529 U.S. at 22–23. The exception to section 405(h)'s channeling requirement then allows "[section] 1331 to fill jurisdictional gaps [the Supreme Court] presumes Congress did not intend." Action Alliance of Senior Citizens v. Leavitt, 483 F.3d 852, 859 (D.C. Cir. 2007).

A.

In analyzing section 405(h), the court first examines whether plaintiffs' action is precluded categorically from agency review. The exception to section 405(h) can apply when another applicable statute or regulation does not permit agency review. Courts have clarified, however, that the ability to channel review through the agency differs from the ability or willingness of the agency to provide the requested remedy. "The fact that the agency might not provide a hearing for that particular contention, or may lack the power to provide one, is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency." Ill. Council,

529 U.S. at 23 (citations omitted); see id. at 24 (explaining the policy justification for agency channeling as "provid[ing] the agency the opportunity to reconsider its policies, interpretations, and regulations in light of those challenges"). After channeling, judicial review provides a sufficient forum to raise statutory or constitutional claims that the agency could not address in the administrative process. See id. at 23–24. A plaintiff cannot simply argue that "administrative review would be futile." Hopewell Nursing, 666 F.2d at 43; see, e.g., Nichole Med. Equip. & Supply, Inc. v. TriCenturion, Inc., 694 F.3d 340, 349–50 & n.16 (3d Cir. 2012). Rather, a plaintiff must demonstrate that, by statute or regulation, the entire category of claims is precluded from agency review. See Council for Urological Interests v. Sebelius, 668 F.3d 704, 708 (D.C. Cir. 2011); Action Alliance, 483 F.3d at 860 (applying the exception because "the Medicare statute appears to provide no avenue for judicial review" of the type of claim at issue); Am. Chiropractic Ass'n v. Leavitt, 431 F.3d 812, 816 (D.C. Cir. 2005).

Plaintiffs argue that CMS regulations would treat the category of claims challenging differential co-payment amounts at preferred and non-preferred pharmacies as a "grievance," for which there is no administrative review. See 42 C.F.R. § 423.560 ("Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested."). CMS responds that it would construe plaintiffs' claim as a coverage determination, not a grievance, and that coverage determinations are amenable to administrative review. See Tabe-Bedward Decl. [D.E. 18-2] ¶ 8.[1]

[1] Defendants appear to concede that there is no administrative review for grievances. Cf. 42 C.F.R. § 423.562(b) (describing the process to address grievances without mentioning a right of agency appeal, while also describing the process to address coverage determination disputes, and delineating an agency and judicial appeal process).

An agency interpretation of its own regulations is usually entitled to deference "even when that interpretation is advanced in a legal brief." Christopher v. SmithKline Beecham Corp., 132 S. Ct. 2156, 2166 (2012); see Chase Bank USA, N.A. v. McCoy, 131 S. Ct. 871, 880 (2011). A court should defer to an agency's interpretation of its own regulations "unless the interpretation is plainly erroneous or inconsistent with the regulations or there is any other reason to suspect that the interpretation does not reflect the agency's fair and considered judgment." Talk Am., Inc. v. Mich. Bell Tel. Co., 131 S. Ct. 2254, 2261 (2011) (quotations and alteration omitted); see Auer v. Robbins, 519 U.S. 452, 461–62 (1997); United States v. Deaton, 332 F.3d 698, 709 (4th Cir. 2003). Plaintiffs argue that CMS's interpretation advanced in the declaration is not entitled to deference because it conflicts with CMS's promulgated materials.

CMS has promulgated regulations and manuals defining coverage determinations and distinguishing them from grievances. See 42 C.F.R. § 423.566(b)(5); CMS, Medicare Prescription Drug Benefit Manual, ch. 18, §§ 20.2, 30.3 (rev. 9, Feb. 2013) ("CMS Manual"), available at http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/. Indeed, the CMS declaration relies on CMS's own regulations and manual for its opinion. See Tabe-Bedward Decl. Moreover, despite plaintiffs' argument, the regulations and manual permit PDP enrollees to seek coverage determinations concerning reimbursement for the difference between co-payment amounts at preferred and non-preferred pharmacies. See, e.g., 42 C.F.R. § 423.566(b)(5) (providing that "[a] decision on the amount of cost sharing for a drug" between a PDP and an individual participant is a coverage determination); CMS Manual § 30.3 ("[P]lan sponsors must process all requests for reimbursement submitted by enrollees (or their representatives . . .) as standard coverage determinations . . . ."); see also CMS Manual § 20.2 ("If the facts don't clearly indicate that a complaint is a grievance, the plan sponsor should process the complaint as a request for a coverage

determination."). Thus, the interpretation expressed in the CMS declaration does not conflict with CMS's promulgated materials, and the court defers to CMS's reasonable interpretation of its regulations. See Nat'l Hospice & Palliative Care Org., Inc. v. Weems, 587 F. Supp. 2d 184, 198–99, 201 (D.D.C. 2008).

In opposition to this conclusion, plaintiffs cite Bowen v. Georgetown University Hospital, 488 U.S. 204 (1988). See Pls.' Resp. [D.E. 20] 25–26. Bowen involved an agency litigating position "wholly unsupported" by any other "regulations, rulings, or administrative practice" and contrary to past agency practice. See Bowen, 488 U.S. at 212–13. In contrast to Bowen, existing agency materials support CMS's interpretation. Thus, Bowen does not aid plaintiffs. Rather, plaintiffs' claim can be channeled through the agency as a coverage determination, which ultimately could be subject to judicial review. See, e.g., Ill. Council, 529 U.S. at 22–23; Puerto Rican, 521 F.3d at 49; Lifestar Ambulance Serv., Inc. v. United States, 365 F.3d 1293, 1297–98 (11th Cir. 2004).

B.

Next, plaintiffs argue that the unique hardship "turns what appears to be simply a channeling requirement into complete preclusion of judicial review." Ill. Council, 529 U.S. at 22–23; see id. at 19 (observing that section 405(h) does not apply when its application "would not simply channel review through the agency, but would mean no review at all"); Council for Urological Interests, 668 F.3d at 713; Nat'l Athletic Trainers' Ass'n v. U.S. Dep't of Health & Human Servs.,455 F.3d 500, 503–07 (5th Cir. 2006); Am. Chiropractic, 431 F.3d at 816. In support, plaintiffs note that as pharmacies, they cannot present a coverage determination appeal to the agency directly. See Defs.' Mem. [D.E. 18-1] 10; Pls.' Resp. 12. Instead, only PDP enrollees may file appeals for coverage determinations. 42 U.S.C. § 1395w-104(h)(1).

The exception to section 405(h) does not apply simply because an individual plaintiff "shows that postponement would mean added inconvenience or cost in an isolated, particular case." Ill. Council, 529 U.S. at 22; see Physician Hosps. of Am. v. Sebelius, 691 F.3d 649, 657–59 (5th Cir. 2012). Although PDP enrollees cannot assign their claims to pharmacies like plaintiffs, the regulations permit enrollees to appoint representatives, including an entity associated with a pharmacy, to pursue the claims on enrollees' behalf. 42 C.F.R. 423.566(c)(2); see Tabe-Bedward Decl. 5. Moreover, the exception to section 405(h) does not apply merely because a plaintiff must rely on a third-party proxy to pursue the administrative claim. See Council for Urological Interests, 668 F.3d at 712; Nat'l Athletic,455 F.3d at 504; Am. Chiropractic, 431 F.3d at 817; Vertos Med., Inc. v. Novitas Solutions, Inc., Civil Action No. H-12-3224, 2012 WL 5943542, at *6 (S.D. Tex. Nov. 27, 2012) (unpublished). Likewise, the exception to section 405(h) does not apply merely because, as here, a third-party cannot fully assign his claim to a plaintiff. See Nat'l Athletic, 455 F.3d at 504 ("We are not persuaded that [plaintiffs'] inability to acquire the [proxy]'s right to administrative review ends our inquiry . . . ."). Furthermore, to the extent plaintiffs suggest that presenting administrative claims for the purposes of challenging the Rule might create civil or criminal liability, see Pls.' Resp. 14, forthright statements of purpose accompanying the administrative claim would negate scienter. See Physician Hosps., 691 F.3d at 658; Nat'l Athletic, 455 F.3d at 505.

Plaintiffs also contend that it would be nearly impossible to amass the requisite claim amounts to initiate administrative and then judicial review. See Pls.' Resp. 21–22; Bizzell Aff. [D.E. 20-3] ¶¶ 7–8. Plaintiffs illustrate this point through co-payment amounts from the Humana Walmart-Preferred Rx Plan, which would require compiling over 50 prescriptions in one tier of medications, or about 200 prescriptions from another tier, or nearly $8,000 worth of prescriptions

from another. See Pls.' Resp. 21.

Part of a PDP enrollee's ability to pursue a claim involves satisfying the amount in controversy requirements for administrative and judicial review. For 2013, the amount in controversy threshold for a hearing before an ALJ is $140.00 and for judicial review is $1,400.00. See 77 Fed. Reg. 59,618 (Sept. 28, 2012); id. at 59,619 (comparison table of threshold amounts for 2009 to 2013). The basic claim amount is the difference between an enrollee's co-payment for a medication at a non-preferred versus a preferred pharmacy. However, claims may be aggregated in several ways to reach the amount in controversy threshold. For example, one enrollee can combine claim amounts for multiple medications, multiple enrollees can combine claim amounts for the same medication, and enrollees may file claims based on the projected value of their co-payments for a medication over the plan year. See 42 C.F.R. § 423.1970(c); CMS Manual § 90.2; see Tabe-Bedward Decl. ¶ 7.

Plaintiffs have not met their burden to show, "as applied generally," the difficulty of meeting the amount in controversy requirement is "likely found in many cases" such that there is "complete preclusion of judicial review." Ill. Council, 529 U.S. at 22–23. Although one plaintiff states that he has never seen a prescription for medication "with a value of $7,500 or more," Bizzell Aff. ¶ 7, such medications do exist. See, e.g., Back v. Sebelius, 684 F.3d 929, 930 (9th Cir. 2012) (referencing a cost of $5940 for a one month supply of one medication); Defs.' Reply 6 (providing examples of medications covered by Part D costing over $4,000 and $6,000 per month). Setting aside high-cost medications, plaintiffs also have failed to demonstrate an inability to meet the amount in controversy by aggregating claimants or medications and using projected annual claim value. Moreover, plaintiffs collectively operate more than four pharmacies and could coordinate to have a standard representative appointed for interested enrollees at all of their pharmacies. See

42 C.F.R. § 423.566(c)(2) (referring only to an "enrollee's appointed representative" without placing further qualifications on the relationship). These steps require time and effort, but a party cannot circumvent section 405(h) "simply because that party shows that postponement would mean added inconvenience or cost." Ill. Council, 529 U.S. at 22. Thus, plaintiffs have failed to show that a third-party proxy cannot present a claim.

In reaching this conclusion about a third-party proxy, the court has considered plaintiffs' argument that a third party has little incentive to bring a claim. See, e.g., Council for Urological Interests, 668 F.3d at 712–13; Nat'l Athletic,455 F.3d at 507; Am. Chiropractic, 431 F.3d at 817; Vertos Med., 2012 WL 5943542, at *6. Analyzing the incentive of third parties to assert a claim is easier with record evidence. See, e.g., Vertos Med., 2012 WL 5943542, at *2, 6. However, the absence of record evidence does not prevent this court from analyzing a third party's incentive to assert a claim. Cf. Ill. Council, 529 U.S. at 22–23 (referring to whether hardship was "likely found in many cases") (emphasis added). In fact, several courts have examined the issue of third-party incentives based on the pleadings.

In American Chiropractic Association, the D.C. Circuit concluded there was sufficient third-party incentive based on hypothetical situations in which chiropractors could convince HMO enrollees to participate in the chiropractors' challenge to Medicare regulations. See Am. Chiropractic, 431 F.3d at 816–17. The court opined that a challenge to a referral requirement for chiropractic services could involve an enrollee paying out-of-pocket for chiropractic services without a referral and then seeking to recover the expense from the HMO, arguing that the referral requirement was impermissible. See id. The court hypothesized that a challenge to an HMO's rule that only doctors and osteopaths could provide chiropractic services would take the same route of an enrollee paying out-of-pocket and then seeking repayment from the HMO. See id. at 817. From

an economic perspective, the court recognized that enrollees could avoid any out-of-pocket cost by the chiropractor waiving a right to payment and becoming the enrollee's assignee. See id. However, both scenarios (particularly the second) implicitly recognized the non-economic incentive of enrollees to seek the services of their chosen health care practitioner notwithstanding an HMO rule directing otherwise. See id.

Similarly, in National Athletic Trainers' Association, the Fifth Circuit held that section 405(h) applied because third-party physicians had sufficient incentive to challenge, on behalf of athletic trainers, a rule precluding Medicare reimbursement for physical therapy provided by athletic trainers. 455 F.3d at 507. The athletic trainers could not present a claim for reimbursement directly, and the trainers could not be the assignees of patients (unlike in American Chiropractic). See id. at 504. But physicians who employed athletic trainers could present a claim for reimbursement for the trainers' services. See id. at 507. Although the court recognized that physicians would incur litigation costs, it concluded that physicians "also [had] financial incentives to challenge the rule," namely the ability to pocket the difference between the Medicare reimbursement and the athletic trainer's wage. Id.

In contrast, in Council for Urological Interests, the D.C. Circuit did not apply section 405(h)'s jurisdictional bar when a potential third-party proxy was "highly unlikely" to pursue an administrative claim because "their unwillingness . . . poses a serious 'practical roadblock' to judicial review." Council for Urological Interests, 668 F.3d at 712. The court examined the complaint and found no "alignment of interests" between the potential third-party proxies and plaintiffs. Id. at 714. Rather, the complaint alleged that there was "no incentive" for the third-party to challenge the regulation and, indeed, that the third-party could benefit financially under the regulation. Id. at 713. Furthermore, the record lacked any evidence that a third-party had

challenged the regulation. Id. Thus, the court applied the exception to section 405(h). Id. at 714.

Plaintiffs argue that they lack access to potential third-party challengers (PDP enrollees), that enrollees lack sufficient economic incentive, and that enrollees generally are not inclined to pursue a challenge. As for access to potential proxies, one plaintiff "consider[s] it highly unlikely that those who chose to enroll in [one particular PDP] even would appear at [his] pharmacy to fill a prescription." Bizzell Aff. ¶ 9. However, the notion that PDP enrollees do not even visit plaintiffs' pharmacies conflicts with the record. See Bizzell Aff. ¶ 4 (stating that, due to preferred pharmacies, it was "very difficult . . . to keep even longtime, loyal customers" but not that enrollees were never present). As for economic incentives, plaintiffs argue that enrollees have no financial incentive to pay a higher co-payment at their non-preferred pharmacies "solely for the purposes of challenging a federal regulation." Pls.' Resp. 18; see Bizzell Aff. ¶ 9. As for non-economic disincentives, plaintiffs assert that their customers, "like others in eastern North Carolina, are averse to litigation, and would be unwilling to be involved in a legal challenge to CMS regulations." Bizzell Aff. ¶ 9; see Pls.' Resp. 18.

Plaintiffs have not met their burden to establish that any hardship they might face in procuring a third-party proxy is, "as applied generally," so widespread that it likely results in "complete preclusion of judicial review." Ill. Council, 529 U.S. at 22–23. Notably, plaintiffs focus almost entirely on the Humana Walmart-Preferred Rx Plan and the difficulties in convincing residents of eastern North Carolina to participate in an administrative challenge. See Pls.' Resp. 17–18 (framing the inquiry as about "enrollees in eastern North Carolina"); Bizzell Aff. ¶¶ 5, 8–9 (discussing loss of business to nearby Walmart locations and the disincentives for "eastern North Carolina" residents to participate in a challenge). But Illinois Council requires a broader inquiry. As of 2012, there were 192 PDPs nationwide besides the Humana Walmart plan, at least some of

which involved preferred networks. Compl. ¶ 30.

Plaintiffs attempt to shift the burden to defendants to demonstrate the incentive of third-parties to pursue a challenge, citing Council of Urological Interests. See Pls.' Resp. 17. However, in Council of Urological Interests, the court acknowledged that its conclusion "flow[ed] from several unique characteristics" of the relationship between the plaintiffs and the potential third-party proxies. Council of Urological Interests, 668 F.3d at 713. Specifically, the class of potential third-party proxies had several, widely-applicable business reasons not to pursue an administrative claim. See id. Here, in contrast, PDP enrollees' incentive to pursue a claim is more affected by varying factors like PDP plan details, relative location of preferred versus non-preferred pharmacies, and customer loyalty. Plaintiffs' allegations, however, are "almost silent" on the possibilities of a challenge outside the contours of the Humana-Walmart plan in eastern North Carolina. See Physician Hosps., 691 F.3d at 659; see also Am. Chiropractic, 431 F.3d at 817.

Under this broader inquiry, plaintiffs have failed to show that the interests of non-preferred pharmacies and PDP enrollees are so misaligned that judicial review is precluded. See Ill. Council, 529 U.S. at 22–23; Council of Urological Interests, 668 F.3d at 713–14. PDP enrollees have the incentive to patronize a non-preferred pharmacy for all the normal, non-economic reasons customers prefer one business to another, such as location, product selection, and customer service. Cf. Compl. ¶ 31 (arguing that "non-preferred" pharmacies are the "pharmacy of choice" for customers). Indeed, the American Chiropractic court recognized an HMO enrollee's non-economic preference for a particular medical service provider as incentive to challenge a policy favoring a different service provider. See Am. Chiropractic, 431 F.3d at 817. Furthermore, a PDP enrollee's non-economic incentive to bring a challenge dovetails with the enrollee's financial incentive. An enrollee patronizing a non-preferred pharmacy naturally would be interested in paying the lower preferred

pharmacy co-payment for a medication and therefore would be inclined to bring a challenge. The financial incentive of PDP enrollees distinguishes these facts from those in Council of Urological Interests, where the potential third-party proxy actually stood to benefit financially if the rule was not challenged. See Council of Urological Interests, 668 F.3d at 713. Finally, the ability of PDP enrollees to appoint a non-preferred pharmacy (or any other designated person or entity) as the representative to prosecute the administrative action would insulate the enrollee from the expense of litigation. Thus, plaintiffs have not met their burden. See, e.g., Ill. Council, 522 U.S. at 22–23; Physician Hosps., 691 F.3d at 659.

The court acknowledges that by requiring plaintiffs to channel their claim through the agency, Congress has imposed an economic hardship on plaintiffs. However, the Supreme Court has stated that an economic hardship is not enough to hurdle the jurisdictional bar that Congress enacted in section 405(h). See, e.g., Ill. Council, 522 U.S. at 13, 23; see also Heckler, 466 U.S. at 627; Fox Ins. Co. v. Sebelius, 381 F. App'x 93, 97 (2d Cir. 2010) (per curiam) (unpublished). Furthermore, the economic hardship from the administrative review process can be mitigated through expedited review. See, e.g., Ill. Council, 529 U.S. at 23–24; GOS Operator, 843 F. Supp. 2d at 1228.

III.

In sum, plaintiffs have not met their burden to establish subject-matter jurisdiction. Accordingly, the court GRANTS defendants' motion to dismiss [D.E. 18] and dismisses the case for lack of subject-matter jurisdiction.

SO ORDERED. This 27 day of March 2013.

JAMES C. DEVER III
Chief United States District Judge